3739

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David Francischelli et al. Examiner: Michael F. Peffley

Serial No.: 10/056,806 Group Art Unit: 3739

Filed: January 25, 2002 Docket No.: M190.135.101

#6 7/16

**Date Due: July 29, 2003**

Title: SYSTEM AND METHOD OF PERFORMING AN ELECTROSURGICAL PROCEDURE



Mail Stop Non-Fee Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450



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We are transmitting herewith the attached:

- ☒ Transmittal Sheet containing Certificate of Mailing (1 pg.).
- ☒ Response (7 pgs.);
- ☐ Other:
- ☒ Two (2) Return Postcards.

If an additional fee is required due to changes to the claims, the fee has been calculated as follows:

| CLAIMS AS AMENDED | | | | | | |
|---|---|---|---|---|---|---|
| | (1) Claims Remaining After Amendment | | (2) Highest Number Previously Paid For | (3) Present Extra | Rate | Fee |
| TOTAL CLAIMS | 31 | - | 31 | 0 | x 18.00 = | $0.00 |
| INDEPENDENT CLAIMS | 3 | - | 3 | 0 | x 84.00 = | $0.00 |
| [ ] MULTIPLE DEPENDENT CLAIMS PRESENTED | | | | | | $0.00 |
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By: Timothy A Czaja
Name: Timothy A. Czaja
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By Timothy A Czaja
Name: Timothy A. Czaja

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## RESPONSE

**Mail Stop [Non-Fee] Amendments**
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450



Dear Sir/Madam:

This is responsive to the Office Action mailed April 29, 2003. In that Office Action, the Examiner rejected claims 1-10, 19, 20, and 22-31 under 35 U.S.C. §102(b) as being anticipated by Panescu et al., U.S. Patent No. 5,688,267 ("Panescu"). Claims 1-3, 24-28, 31, and 33 were rejected under 35 U.S.C. §102(b) as being anticipated by Whayne et al., U.S. Patent No. 5,843,411 ("Whayne"). The Examiner also rejected claims 2-11, 15, and 22-31 under 35 U.S.C. §103(a) as being unpatentable over Panescu in view of Whayne. Claims 16-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu and Whayne and further in view of Mulier et al., U.S. Patent No. 5,897,553 ("Mulier"). Claim 21 was rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu in view of Jackson et al., U.S. Patent No. 5,383,874 ("Jackson") and Edwards, U.S. Patent No. 6,009,877 ("Edwards"). Finally, the Examiner rejected claims 12-14 as being dependent upon a rejected base claim, however, the indication that these claims would be allowable if rewritten in independent form is noted with appreciation. With this Response, claims 1-31 remain pending in the Application and are presented for reconsideration and allowance in view of the arguments presented below.

## Claim Rejections under 35 U.S.C. §§ 102 & 103

Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by Panescu et al., U.S. Patent No. 5,688,267 ("Panescu") and under 35 U.S.C. §102(b) as being anticipated by Whayne et al., U.S. Patent No. 5,853,411 ("Whayne"). Claim 1 relates to a method of making a lesion at

living tissue at a target site. The method includes providing an electrosurgical system having an electrosurgical instrument with an electrode and a power source with multiple settings, determining a desired depth for the lesion, selecting a desired power setting, and applying electrical energy to the electrode in contact with the living tissue. The energy is applied to the living tissue for a recommended energization time period based upon the desired lesion depth and the selected power setting. Such limitations are not taught or otherwise suggested by any of the cited references.

In particular, Panescu relates to a method for sensing multiple temperature conditions during tissue ablation. The method of Panescu includes pre-selecting a targeted ablation time as well as a maximum power and maximum temperature (column 11, lines 6-61). Based upon these inputs, the method of Panescu selects a fixed power level "P" and a sensed temperature "$T_1$" to be maintained by a variable cooling rate (column 11, lines 21-35). Panescu teaches using a predetermined or selected time period to identify the proper power setting for the subsequent ablation process. As such, the time period is determined prior to selection of a power setting. This teaching is the converse of the limitations of claim 1, in which the recommended energization time period is based upon a selected power setting. For at least the above described reasons, Panescu fails to teach or otherwise suggest the limitations of claim 1.

Whayne fails to significantly alter this analysis. Similarly to Panescu, Whayne utilizes temperature sensors on the electrode structure to determine the actual temperature of the electrode and/or of the surrounding tissue (column 25, lines 30-40). The temperatures sensed by the sensors of Whayne are used to adjust the time and power level to achieve desired lesion patterns (column 25, lines 37-40). Therefore, Whayne teaches regulation of variable time and power levels as independent parameters based upon the temperature sensed by the sensors. As such, Whayne fails to teach or otherwise suggest a recommended energization time period based upon the selected power setting as recited in claim 1.

For at least the above described reasons, none of the cited references teach or otherwise suggest the limitations of claim 1. Accordingly, claim 1 is believed to be allowable.

Claims 2-10, 19, and 20 were rejected under 35 U.S.C. §102(b) as being anticipated by Panescu, and claims 2 and 3 were also rejected under 35 U.S.C. §102(b) as being anticipated by

Whayne. In addition, claims 2-11 and 15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu in view of Whayne. Each of claims 2-10, 19, and 20 depend from claim 1. As described above, none of the cited references teach or otherwise suggest the limitations of claim 1. As a result, dependent claims 2-10, 19, and 20 are similarly believed to be allowable over the cited references.

Claims 16-18 were rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu and Whayne and further in view of Mulier. Claim 21 was rejected under 35 U.S.C. §103(a) as being unpatentable over Panescu in view of Jackson and Edwards. Each of claims 16-18 and 21 depends from amended claim 1, which as previously described recites allowable subject matter. As such, Mulier, Jackson, and Edwards fail to alter the analysis. Consequently, dependent claims 16-18 and 21 are also believed to be allowable subject matter.

Independent claim 22 was rejected under 35 U.S.C. §102(b) as being anticipated by Panescu and under 35 U.S.C. §103(a) as being unpatentable over Panescu in view of Whayne. Independent claim 22 relates to an electrosurgical system for performing an electrosurgical procedure on living tissue. The system includes an electrosurgical instrument, a power source, and an energization look-up table. The power source has multiple available power settings and is electrically connected to the electrosurgical instrument. The energization look-up table corresponds with the electrosurgical instrument and includes a power setting data set, a lesion depth data set, and energization time period information organized as a function of the power setting and lesion depth data sets. The power setting data set includes at least one of the multiple available power settings of the power source. The energization look-up table is adapted to identify a recommended energization time period based upon a cross-reference of a selected power setting relative to the power setting data set and a desired lesion depth relative to the lesion depth data set. For similar reasons as described with respect to claim 1, none of the cited references teach or otherwise suggest such limitations.

In particular, similarly as described above, Panescu teaches determining a proper power setting based on a predetermined time period in direct contrast to the limitations of claim 22, which identifies a recommended energization time period based on a selected power setting. In addition, Panescu incorporates multiple temperature sensors to determine actual temperature

conditions during tissue ablation. As such, Panescu teaches the lesion depth "$D_{50C}$" as being a function of the physical characteristics of the electrode, the angle the electrode is applied to the tissue, the temperature "$T_1$" of the electrode, the power "P" transmitted by the electrode, and the time "t" the tissue is exposed to the power "P" (column 9, lines 5-15). As such, Panescu only speaks of the relationship between these parameters as a depth function, or more particularly, a $D_{50C}$ function. Accordingly, the matrixes of Panescu present depth "$D_{50C}$" as a function of the temperature "$T_1$," the power "P," and the time "t" (see column 10). Since Panescu only teaches organization of ablation condition data as a depth function, Panescu fails to teach or otherwise suggest energization time period information organized as a function of the power setting and lesion depth data sets as required by the limitations of claim 22.

Also as described above, Whayne fails to alter this analysis as Whayne teaches variable time and power levels rather than a recommended energization time period based on a selected power setting. Under similar reasoning, Whayne also fails to teach or otherwise suggest other limitations of claim 22 such as the energization time period information being organized as a function of the power setting data set or an energization look-up table adapted to identify a recommended energization time period based upon a cross-reference of a selected power setting relative to the power setting data set. As such, claim 22 is not taught or otherwise suggested by the cited references.

Due at least in part to the reasons described above, none of the cited references teach or otherwise suggest the limitations of independent claim 22. As a result, claim 22 is believed to be allowable.

Claims 23-27 were rejected under 35 U.S.C. §102(b) as being anticipated by Panescu and under 35 U.S.C. §103(a) as being unpatentable over Panescu in view of Whayne. Claims 24-27 were also rejected under 35 U.S.C. §102(b) as being anticipated by Whayne. Each of claims 23-27 depend from independent claim 22. As previously described, claim 22 is believed to be allowable over the cited references. Accordingly, dependent claims 23-27 are also believed to be allowable.

In addition, claim 24 recites additional, patentably distinct subject matter. Claim 24 recites the system of claim 22 further including a fluid source fluidly connected to an internal

lumen of the electrosurgical instrument. The fluid source is configured to supply a liquid to a region of the electrode at an irrigation rate during an electrosurgical procedure. Further, the energization look-up table correlates the energization time period information with a desired irrigation rate. Panescu teaches away from such limitations. In particular, Panescu teaches an electrosurgical procedure incorporating temperature sensors. The cooling rate is varied throughout the procedure in an attempt to maintain the temperature "$T_1$" of the ablation site for a pre-selected time period "t" (column 11, lines 5-42). Since Panescu utilizes a variable cooling rate as its sole method maintaining "$T_1$" for a pre-selected time period, Panescu teaches away from an energization look-up table that correlates the energization time period information with a desired irrigation rate, as recited in claim 24.

Independent claim 28 was rejected under 35 U.S.C. §102(b) as being anticipated by Panescu and Whayne and under 35 U.S.C. §103(a) as being unpatentable over Panescu in view of Whayne. Independent claim 28 relates to an electrosurgical system for performing an electrosurgical procedure. The system includes an electrosurgical instrument having an electrode and a distal portion, a power source electrically connected to the electrosurgical instrument for selectively energizing the electrode, and a controller. The power source has multiple available settings. The controller is for electrically selecting a recommended energization time period by reference to predetermined length of time information that relates to the electrosurgical instrument and based upon a selected power setting and a desired lesion depth. For similar reasons as described with respect to claims 1 and 22, none of the cited references teach or otherwise suggest the limitations of claim 28.

For example, Panescu teaches pre-selecting a targeted ablation time, a maximum power, and a maximum temperature prior to beginning the electrosurgical procedure (column 11, lines 6-61). Using these chosen values as input, the controller of Panescu selects a fixed power level and a temperature to be maintained by the cooling rate. As such, the ablation time is determined before the power level is ascertained. This is in direct contrast to the limitations of claim 28 which includes a controller for selecting a recommended energization time period by reference to information based upon a selected power setting. Furthermore, Whayne chooses the time and the power levels independently based upon the ablation temperatures determined by the temperature

sensors. As a result, Whayne also fails to teach or suggest choosing the energization time period based upon the power setting and the lesion depth. Thus, claim 28 is believed to be allowable.

Claims 29-31 were rejected under 35 U.S.C. §102(b) as being anticipated by Panescu and/or Whayne and under 35 U.S.C. §103(a) as being unpatentable over Panescu in view of Whayne. Each of claims 29-31 depends from independent claim 28. As previously described, claim 28 is not taught or otherwise suggested by any of the cited references and is believed to be allowable. In addition, claim 30 recites further patentably distinct subject matter for similar reasons as described with respect to claim 24. For at least these reasons, claims 29-31 are believed to be allowable.

**Allowable Subject Matter**

Claims 12-14 identified by the Examiner as being allowable subject matter, but rejected for being dependent upon a rejected base claim. Claims 12-14 depend from independent claim 1, which, as described above, is believed to be allowable. Therefore, claims 12-14 are no longer dependent upon a rejected base claim and are believed to be allowable.

## CONCLUSION

In light of the above, Applicant believes independent claims 1, 22, and 28 and the claims depending therefrom, are in condition for allowance. Allowance of these claims is respectfully requested.

No fees are required under 37 C.F.R. 1.16(b)(c). However, if such fees are required, the Patent Office is hereby authorized to charge Deposit Account No. 500471.

The Examiner is invited to contact the Applicants' Representative at the below-listed telephone number if there are any questions regarding this response.

Respectfully submitted,

David Francischelli et al.,

By their attorneys,

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CERTIFICATE UNDER 37 C.F.R. 1.8: The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail, in an envelope address to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 3rd day of July, 2003.

By
Name: Timothy A. Czaja